NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., ET AL., Defendants.	:	CIVIL ACTION NO. 04-2355 (JLL)

LINARES, District Judge.

Plaintiffs Altana Pharma AG ("Altana") and Wyeth sued defendants Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries, Ltd. (collectively "Teva"), and Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Advance Research Centre, Ltd. (collectively "Sun") for infringement of claims 22 and 25 of United States Patent No. 4,758,579 (the " '579 patent"). Currently before the Court is Plaintiffs' motion for a preliminary injunction[1] filed on June 22, 2007. The Court has reviewed the parties' submissions and heard oral argument on the instant motion on July 31, 2007. For the following reasons, the Court denies Plaintiffs' motion for a preliminary injunction.

I. Factual and Procedural History

Altana is the owner of the '579 patent, which issued on February 9, 1988. Wyeth is the exclusive licensee of the '579 patent in the United States. The '579 patent discloses the compound

[1] Plaintiffs also asked the Court to enter a temporary restraining order. This request is moot in light of the parties' agreement, on the record on July 31, 2007, to maintain the status quo until September 7, 2007, in order to give the Court sufficient time to render its decision on the instant motion.

pantoprazole, the active ingredient in Plaintiffs' drug Protonix.[2] Protonix is a type of proton pump inhibitor ("PPI") which inhibits the secretion of gastric acid in the stomach. Protonix is prescribed to treat various gastrointestinal disorders including gastroesophageal reflux disease, which causes heartburn and chronic, erosive ulcers in the esophagus.

A. Development of Pantoprazole

In the 1970s, Dr. George Sachs, who worked for a pharmaceutical company called AB Hassle, which later became AstraZeneca, discovered that certain compounds were acid-activated prodrugs which could be arranged to inhibit or shut off the proton pump in the stomach and thus, inhibit the production of gastric acid. Dr. Sachs's work lead to AB Hassle's development of omeprazole, the first commercial PPI in 1979. Omeprazole was approved by the Food and Drug Administration ("FDA") in 1989 and marketed as Prilosec. The patent covering omeprazole is United States Patent No. 4,255,431 (the " '431 patent").

In the wake of the development of omeprazole, many drug companies, including Altana,[3] began working to develop their own PPIs to compete in the market. The efforts to produce a PPI superior to omeprazole involved numerous drug companies, hundreds of scientists, and the creation of thousands of potential PPI compounds. Ultimately, only five PPI compounds survived clinical trials and received FDA approval: omeprazole (Prilosec), pantoprazole (Protonix), lansoprazole (Prevacid), rabeprazole (Achiphex), and esomeprazole (Nexium).

All of the PPI candidate compounds, including the five listed above, share the same basic chemical backbone, which consists of three core parts. On the left side of the PPI backbone is a

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[2] The parties do not dispute the construction of the relevant claims. Claim 22 discloses pantoprazole and its pharmacologically compatible salt. Claim 25 is limited to the sodium salt of pantoprazole.

[3] At that time, Altana was called "Byk Gulden."

benzimidazole group. On the right side of the backbone is a pyridine group. Chemists number the positions on each group or ring. The benzimidazole and pyridine groups are connected via the methylsulfinyl bridge.[4] Using this backbone as a predicate, the drug companies working to develop effective PPIs experimented with substituting different chemical groups on the different positions on the benzimidazole and pyridine rings.

In an effort to discover an effective PPI, Altana created its own PPI development team composed of synthetic chemists.[5] Ultimately, Altana patented a class of eighteen PPI compounds with fluorine-based substituents on the benzimidazole ring. These compounds issued as United States Patent No. 4,555,518 (the " '518 patent"). In 1984, an Altana scientist named Dr. Bernard Kohl, who was not a member of the PPI development team, but instead was involved in making large-scale quantities of compounds after such were invented by the Altana development teams, purportedly invented pantoprazole. Altana apparently allowed Dr. Kohl to perform synthetic chemical work as an aside to his traditional scale-up duties. Dr. Kohl claims he invented pantoprazole by synthesizing a compound having two methoxy ($-OCH_3$) groups attached to the pyridine ring of the PPI backbone. This is referred to as a "dimethoxy pyridine PPI." Pantoprazole is undisputably identical to compound 12 of the '518 patent except that compound 12 has a methyl group ($-CH_3$) at the 3-position of the pyridine ring and pantoprazole has a methoxy group at that position.[6] The other methoxy group, which

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[4] For a diagram of the PPI backbone, see Teva's Opposition Brief at page 11.

[5] Synthetic chemists are responsible for the design and synthesis of chemical compounds.

[6] A methoxy group is a type of alkoxy group. An alkoxy group is an alkyl group that has an oxygen atom. An alkyl group is a substituent comprised of carbon and hydrogen. Methyl is a type of alkyl group.

appears in both pantoprazole and compound 12, is at the 4-position of the pyridine group.[7]

B. Prosecution of the '579 Patent

Altana filed the patent application claiming pantoprazole in the United States Patent and Trademark Office ("PTO") in June 1985. The application was reviewed by Examiner Jane T. Fan, who examined numerous other patent applications claiming PPI compounds during the relevant time period. Examiner Fan initially rejected all claims of the '579 patent as obvious over two other Altana patents, the '518 patent and United States Patent No. 4,650,693, and over the '431 patent which discloses omeprazole. Furthermore, Examiner Fan rejected all claims as unpatentable under the doctrine of obviousness-type double patenting over claims of United States Patent No. 4,686,230 (the " '230 patent"). Following responses by Altana, Examiner Fan repeated these rejections several times during the course of the patent prosecution.

Examiner Fan ultimately withdrew her objections and the patent issued on February 9, 1988 as the '579 patent. The exact reason for the withdrawal of her objections is not clear from the record. Examiner Fan did not attach a statement of reasons as to why she withdrew her obviousness objections. It appears that she withdrew her obviousness objections after Altana submitted data indicating that the compounds in the '579 patent were comparable in potency to the requisite prior art compounds, which Examiner Fan identified as the '518 patent compounds, but exhibited a superior pH5 stability compared to those compounds.[8] With respect to her initial obviousness-type double patenting

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[7] For a diagramed comparison of compound 12 and pantoprazole, see Teva's Opposition Brief at page 13.

[8] pH is a compound's measure of acidity on a scale of 1-14, with a pH1 being the most acidic environment, pH7 being neutral, and a pH14 being the least acidic environment. The parietal cells in the human stomach have a pH of 1 and thus, are very acidic. Throughout the human body, cellular environments that a PPI might encounter once ingested or injected can have a pH as low as 5. Such environments are slightly acidic. Thus, for a PPI to be most effective, and produce the least side effects in areas of the human body besides the stomach, the idea was

concerns, Examiner Fan stated, in withdrawing this objection, that the "double patenting objection will be withdrawn since '230 differs from the claimed compound" and that she "relied on all claims of the '230 patent not just claim 5" in considering the double patenting issue.

C. Protonix is Commercially Available

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000.[9] Plaintiffs claim that pantoprazole is the most successful drug product ever developed by Altana, generating approximately $2 billion in sales each year. The parties dispute the causes of such success. Plaintiffs claim that Protonix is superior to other PPIs, and thus, generates substantial revenues because Protonix has unique properties which result in various clinical advantages over other PPIs, such as longer duration of action, better acid control at night, and a lower potential for interaction with other drugs. Defendants claim that the success of Protonix is not due to its clinical superiority (and in fact, argue that Protonix has no known advantage over other PPIs), but that such is due to Plaintiffs' aggressive marketing strategy and offering the drug at a deep discount.

D. Teva and Sun Seek FDA Approval for Generic Versions of Protonix

On or about April 6, 2004, Teva filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act,[10] seeking FDA approval to sell a generic version of Protonix prior

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that a compound should be stable at pH5 but reactive at pH levels lower than 5. This would cause the PPI to accumulate and remain in the parietal cells, thus inhibiting acid secretion in the stomach.

[9] It appears that the FDA approved the 40 mg base tablet version of pantoprazole on February 2, 2000 and subsequently approved the injectable version on March 22, 2001 and the 20 mg base table version on June 12, 2001. See Approved Drug Products (27th Ed. 2007) at 3-290 (Lockner Declaration, Exhibit 118).

[10] The Hatch-Waxman Act is formally called the "Drug Price Competition and Patent Term Restoration Act of 1984," Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355 and 360cc and 35 U.S.C. §§ 156 and 271). For a thorough discussion of the Act, its purpose, and its operation, see Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1325-27 (Fed. Cir. 2003).

to the expiration of the '579 patent.[11] On or about March 1, 2005 and June 25, 2005, Sun filed ANDA applications also seeking the FDA's approval to sell generic versions of Protonix prior to the expiration of the '579 patent. Both Teva and Sun filed paragraph IV certifications in accordance with their ANDA applications. By filing paragraph IV certifications, Teva and Sun claimed that their generic drugs either do not infringe the '579 patent or that the '579 patent is otherwise invalid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

E. Plaintiffs Sue Teva and Sun for Infringement of the '579 Patent

Plaintiffs responded by suing Teva and Sun for infringement of the '579 patent. Plaintiffs filed a complaint against Teva on May 20, 2004 (Civil Action No. 04-2355). Plaintiffs subsequently sued Sun for infringement of the '579 patent (Civil Action Nos. 05-1966 and 05-3920).[12] The Court consolidated Plaintiffs' claims against Sun with their previously-filed lawsuit against Teva by orders dated June 20, 2005 and June 13, 2006.[13]

Plaintiffs' filing of the instant lawsuits against Teva and Sun invoked an automatic stay under the Hatch-Waxman Act which prohibits the FDA from approving the generic drugs until: the '579 patent expires, the Court enters judgment in the infringement lawsuit, or thirty months elapse since Altana received notification of each ANDA Paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iii); Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1327 (Fed. Cir. 2003). At the time such lawsuits

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[11] The '579 patent expires on July 19, 2010.

[12] Plaintiffs filed two separate lawsuits against Sun. The first complaint, filed on April 13, 2005, alleged that Sun's ANDA filing with respect to the tablet form of Protonix infringed the '579 patent. The second complaint, filed August 5, 2005, alleged that Sun's ANDA filing with respect to an injectable form of Protonix infringed the '579 patent.

[13] The Court also consolidated Plaintiffs' lawsuit against another generic drug company, KUDCo., Civil Action No. 06-3672, into the instant case. However, KUDCo. is not involved in the instant preliminary injunction proceedings.

were filed, Plaintiffs were aware that the Hatch-Waxman Act stay as to Teva would expire on August 2, 2007[14] and the stay as to Sun would expire on September 4, 2007. Upon expiration of the respective Hatch-Waxman Act stays, the FDA would be free to approve Teva's and Sun's generic versions of Protonix and such could be sold to the public.

F. **Plaintiffs File Motion for Preliminary Injunction**

Aware that their market exclusivity as to Protonix was threatened by the expiration of the Hatch-Waxman Act stays preventing FDA approval of Teva's and Sun's generic drugs, in approximately early June 2007, Plaintiffs asked Teva and Sun if they intended to launch generic versions of Protonix upon the expiration of the stay period and subsequent FDA approval. Teva affirmatively represented to Plaintiffs that it intended to launch a generic version of Protonix upon expiration of the stay and FDA approval. Such a launch would be considered an "at risk launch" because this Court has not yet rendered a decision on Plaintiffs' underlying infringement claim. Sun informed Plaintiffs and the Court, in a July 5, 2007 letter, that "Sun has no current plans to launch its generic pantoprazole product after September 4, 2007 and before a final decision in this case on the merits, but will reconsider its decision if Teva prevails on plaintiffs' preliminary injunction motion and if Teva does launch its generic product."

Plaintiffs subsequently filed a motion for a preliminary injunction against Teva and Sun on June 22, 2007. Teva filed an opposition to this motion, conceding infringement of the '579 patent, but arguing that the motion should be denied because Teva has raised a substantial question as to the validity of the '579 patent based on obviousness and obviousness-type double patenting. Sun asked the Court to dismiss Plaintiffs' preliminary injunction motion as to Sun or postpone the date by which Sun

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[14] FDA approval of Teva's generic version of Protonix was actually stayed for forty-two months due to operation of a separate statutory requirement. See 21 U.S.C. § 355(j)(5)(F)(ii).

must submit its opposition to some date after the Court issues a decision on Plaintiff's motion as to Teva. Sun claimed, in its July 5, 2007 letter, that since Sun has not affirmatively represented that it plans to launch its product and, even if Sun had plans to launch, they cannot do so until at the earliest, September 4, 2007, there is "simply no actual or imminent infringement by Sun in connection with plaintiffs' preliminary injunction motion against Sun and thus, there exists no actual case or controversy against Sun." The Honorable Claire C. Cecchi, United States Magistrate Judge, entered an order on July 18, 2007 stating that Plaintiffs' preliminary injunction motion shall proceed against Sun. Sun subsequently filed an opposition to the motion, also conceding infringement of the '579 patent, but arguing that the patent was invalid for obviousness-type double patenting.[15]

The Hatch-Waxman Act stay expired as to Teva on August 2, 2007 and expired as to Sun on September 4, 2007. It appears that on August 2, 2007, the day Teva's stay expired, the FDA granted final approval to Teva to market its generic version of Protonix. Since the Hatch-Waxman Act stay as to Sun has also expired, the FDA is now free to approve Sun's generic version of Protonix; however, to the Court's knowledge, such approval has not yet been granted. Despite the fact that the FDA has already approved Teva's generic version of Protonix, and that the FDA is now free to approve Sun's generic drug, all parties to this action agreed, on the record on July 31, 2007, not to launch generic versions of Protonix until September 7, 2007, in order to give the Court time to consider the instant motion, see supra note 1.

The Court has reviewed the parties' briefs, as well as the attached declarations, exhibits, and other submissions. Further, the Court heard oral argument on the instant motion and has reviewed the

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[15] Although Sun did not explicitly oppose Plaintiffs' preliminary injunction motion on obviousness grounds and instead, only briefed obviousness-type double patenting, any findings of a substantial question as to the validity of the '579 patent based on obviousness would apply similarly to Sun as to Teva and thus, the Court treats Sun as having raised an obviousness defense. Sun did raise an obviousness defense in its answers to Plaintiffs' complaints.

transcript of such argument. Below is a discussion of the standard of review, the relevant legal principles, and the Court's factual and legal findings.

II. Standard of Review

Preliminary injunctions are extraordinary remedies that are not routinely granted. See, e.g., National Steel Car, Ltd. v. Canadian Pacific Ry., Ltd., 357 F.3d 1319, 1324 (Fed. Cir. 2004). The decision to grant a preliminary injunction is within the sound discretion of this Court. Abbott Labs v. Andrx Pharmaceuticals, Inc., 452 F.3d 1331, 1334 (Fed. Cir. 2006). The Court examines the following four factors in determining whether injunctive relief should be granted:

(1) whether the movant has shown a reasonable probability of success on the merits;
(2) whether the movant will be irreparably harmed by denial of the injunctive relief sought;
(3) whether the threatened injury to the movant if an injunction is not granted outweighs the threatened harm to the non-movant if the injunction is granted; and
(4) the impact of a preliminary injunction on the public interest.

See, e.g., Abbott Labs., 452 F.3d at 1334; National Steel Car, 357 F.3d at 1324-25.

Plaintiffs have the burden to demonstrate that a preliminary injunction should be granted. See, e.g., Abbott Labs., 452 F.3d at 1334. Although the Court must generally weigh all four of these factors, "a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." See Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001); Novartis Corp. v. Teva Pharm. USA, Inc., Nos. 04-4473, 06-1130, 2007 WL 1695689, at *3 (D.N.J. June 11, 2007).

III. Legal Discussion

A. Likelihood of Success on the Merits

In order to establish likelihood of success on the merits, Plaintiffs must show that Defendants' invalidity defenses lack substantial merit. See Abbott Labs., 452 F.3d at 1335. In other words, if

Defendants have raised a substantial question of invalidity, Plaintiffs are not entitled to a preliminary injunction. See Abbott Labs., 452 F.3d at 1335; see also Amazon.com, 239 F.3d at 1350-51 (stating that if the patentee "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue").

In making this determination, the Federal Circuit has emphasized that the Court's finding as to likelihood of success on the merits at the preliminary injunction stage is just that—preliminary. Specifically, the Federal Circuit has stated "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." Amazon.com, 239 F.3d at 1358; see also Novartis, 2007 WL 1695689, at *3 & n.8 (indicating that a district court's finding that defendant has raised a substantial defense does not mean that the defendant will carry its burden at trial to prove invalidity based on clear and convincing evidence). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." Amazon.com, 239 F.3d at 1359; see also Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc., Nos. 04-1689, 06-757, 2006 WL 3019689, at *2 (D.N.J. Oct. 23, 2006).

This Court first considers whether Plaintiffs have shown that Defendants' obviousness defense lacks substantial merit. Pursuant to 35 U.S.C. § 103(a), a patent may not be obtained from the PTO if the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." The obviousness question is a legal one, based on underlying factual determinations. See, e.g., PharmaStem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 1359 (Fed. Cir. 2007). Factual determinations that are relevant to the

obviousness inquiry are: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations or objective indicia of non-obviousness. See, e.g., id.

The United States Supreme Court recently recognized, in KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007) that almost all inventions "rely on building blocks long since uncovered" and therefore, are "combinations of what, in some sense, is already known." The Court thus concluded that a patent is not obvious simply because each of its elements was independently known in the prior art. Id. Instead, in evaluating whether the subject matter of a patent claim is obvious, courts must look at the *objective reach* of the claim and whether such extends to what is obvious. See id. at 1741-42. The KSR court rejected a rigid and formalistic application of the Federal Circuit's "teaching, suggestion, and motivation" test, pursuant to which a patent claim was obvious if there was some motivation or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the art, to combine the prior art teachings as such were combined by the inventor." See id. at 1734, 1741; see also Crown Operations Int'l Ltd. v. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002) (discussing the Federal Circuit's teaching, suggestion, and motivation test pre-KSR).

The Supreme Court indicated in KSR that in conducting an obviousness analysis, courts must apply a common sense approach, looking at all of the circumstances, and considering any inferences or creative steps that a person of ordinary skill in the art would have employed to determine "whether there was an *apparent reason* to combine the known elements in the fashion claimed by the patent at issue." KSR, 127 S. Ct. at 1740-42 (emphasis added). The Court emphasized that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." Id. at 1742. Furthermore, the

KSR Court indicated that obviousness may be established by showing that a combination of elements was obvious to try. The KSR Court stated:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance, the fact that a combination was obvious to try might show that it was obvious under § 103.

Id.

In a post-KSR opinion, Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. June 28, 2007), the Federal Circuit emphasized that its test for prima facie obviousness for chemical compounds "is consistent with the legal principles enunciated in KSR." Pursuant to the Federal Circuit's approach in this regard, " 'structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness.' " Takeda, 492 F.3d at 1356 (quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990)). This approach, according to the Federal Circuit, is consistent with KSR because "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." Id. at 1357.

Defendants claim that the '579 patent was obvious because the teachings of a 1984 journal article by Dr. Sachs (the "Sachs article") and a 1960 journal article by Dr. A. Bryson (the "Bryson article") provide an apparent reason for modifying the chemical structure of compound 12 of the '518 patent by substituting a methyl group for a methoxy group on the 3-position on the pyridine ring to create pantoprazole. In particular, Defendants claim that the structure of compound 12 was the starting point for further development, that the Sachs article provided motivation for modifying compound 12

in the manner modified, and that the Bryson article provided the tools as to how to so modify compound 12. The Court herein considers whether Defendants have raised a substantial question as to obviousness, relying on the standards set forth in KSR and Takeda, and making the necessary factual determinations.[16]

First, the Court must determine who is a person of ordinary skill in the art. This is not in dispute. The parties agree that a person of ordinary skill in the art is a medicinal chemist.[17]

Second, the Court must examine the differences between the claimed invention and the prior art. This is also not in dispute. The claims of the '579 patent at issue here, namely, claims 22 and 25, disclose the active ingredient for pantoprazole. Pantoprazole differs from the relevant prior art, compound 12 of the '518 patent, in that pantoprazole has a methoxy group at the 3-position of the pyridine ring and compound 12 has a methyl group at that position. The PPI backbone and all other substituents in pantoprazole and compound 12 are identical.

Third, the Court must make a preliminary finding as to whether one of ordinary skill in the art

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[16] To the extent that the PTO already made a determination of non-obviousness, such a finding makes the defendant's burden of proving invalidity at trial "especially difficult." See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1375 (Fed. Cir. 2006). In this case, it is undisputed that Examiner Fan of the PTO considered the obviousness of pantoprazole over compound 12 of the '518 patent; but, she did not consider the Sachs or Bryson articles, which are integral pieces of the obviousness defenses in this case. Thus, this Court does not afford any particular deference to Examiner Fan's decision to issue the '579 patent over her initial obviousness objections. See PharmStem Therapeutics v. Viacell, Inc., 491 F.3d 1342, 1366 (Fed. Cir. 2007) ("When the party asserting invalidity relies on references *that were considered during examination or reexamination*, that party 'bears the added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job.' " (emphasis added) (internal quotation omitted)). Furthermore, as indicated above, Examiner Fan failed to provide the reasons why she withdrew her initial obviousness objections.

[17] Since the parties do not elaborate on the definition of one skilled in the art in this case, the Court will not provide a more extensive definition. In any event, more specification is unnecessary, as the requirement, in practice, reminds judges to put themselves in the shoes of one skilled in the art, as opposed to compelling a particular factual finding. Cf. Janssen Pharmaceutica N.V. v. Mylan Pharmaceuticals, Inc., 456 F. Supp. 2d 644, 653-54 (D.N.J. 2006).

would have selected compound 12 of the '518 patent as a lead compound, i.e., one that would be "most promising to modify" in order to create a superior PPI drug. Despite Defendants' protestations to the contrary, KSR did not effectively overrule the Federal Circuit's decision in Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1344 (Fed. Cir. 2000), in which the court indicated that to prevail on an obviousness claim involving structurally similar chemical compounds, the defendant must show that the plaintiff had a motivation for selecting the prior art compound as a lead compound.

In Takeda, which, as discussed above, is a post-KSR opinion from the Federal Circuit, the court stated that "in cases involving new chemical compounds, it remains necessary [post-KSR] to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new chemical compound." Takeda, 492 F.3d at 1357. The Takeda court found that the defendant in that case, Alphapharm, did not establish a prima facie case of obviousness because it failed to show that "the prior art would have led to the selection of compound b as a lead compound." Id. at 1362-63 ("The court properly concluded that Alphapharm did not make out a prima facie case of obviousness because Alphapharm failed to adduce evidence that compound b would have been selected as the lead compound . . . ."). In defining the phrase "lead compound," the Federal Circuit indicated that such refers to *compounds* in the prior art that would be "most promising to modify," thus implying that there may be more than one potential "lead compound" choice to support a claim of obviousness (i.e., if there were several compounds that were the "most promising to modify"). Id. at 1357. Accordingly, the Court herein examines whether Defendants have raised a substantial question as to whether compound 12 was a logical choice as a lead compound.[18]

[18] To the extent that the lead compound requirement did not survive KSR, the Federal Circuit made clear in Takeda that at the very least, to prevail on an obviousness claim, the defendant must show that there was a "reason that would have led a chemist to modify a *known*

Although Plaintiffs now claim that omeprazole was the "gold standard" for further PPI development during the time pantoprazole was invented, Altana admitted in its application for the '518 patent that the compounds in that patent, including compound 12, were significant improvements over the prior art and thus, that such were the state of the art and superior to omeprazole. Specifically, Altana told the PTO that "the excellent properties of the compounds according to the invention prove to be significantly superior to those of the compounds known for the prior art." See United States Patent Application No. 4,555,518 at p. 22. Out of the eighteen compounds disclosed in the '518 patent, compound 12 was one of the more potent compounds and thus, was one of the more promising compounds to modify. See Mitscher Declaration at ¶¶ 93-94. Further, in reviewing the '579 patent application, Examiner Fan used the '518 compounds, including compound 12, as references. Based on the foregoing, Defendants have raised a substantial argument that compound 12 was a natural choice for further development in this regard. See KSR, 127 S. Ct. at 1742 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."). The Court recognizes that this finding contradicts Dr. Kohl's testimony that he invented pantoprazole not by using compound 12 as a predicate, but by using an unwanted by-product from his scale-up work as a starting point. However, the Court again emphasizes that its findings herein are preliminary. Defendants will be held to a higher burden of proof in this regard—clear and convincing evidence—at trial on their obviousness defense.

Next, the Court must determine the scope and content of the prior art at issue, namely, the Sachs and Bryson articles, and whether such, as Defendants suggest, created an apparent reason for

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compound in a particular manner to establish prima facie obviousness of a new chemical compound." Takeda, 492 F.3d at 1357 (emphasis added). It is not in dispute that compound 12 of the '518 patent was a *known compound* at the time pantoprazole was invented.

modifying compound 12 by substituting a methyl group for a methoxy group at the 3-position of the pyridine ring to create pantoprazole. See Takeda, 492 F.3d at 1362-63 ("Alphapharm did not make out a prima facie case of obviousness because Alphapharm failed to adduce evidence that compound b would have been selected as the lead compound and, even if that preliminary showing had been made, it failed to show that there existed a reason, based on what was known at the time of the invention, to perform the chemical modifications necessary to achieve the claimed compounds.").

Dr. Sachs's 1984 article, entitled,"Pump Blockers and Ulcer Disease," states in relevant part:

> Consideration of the properties of the parietal cell suggests some design features for a selective inhibitor of gastric ATPase.[19] The secretory canaliculus, into which acid is secreted by the ATPase, can be regarded as a membrane-bound region of low pH. Such a space should accumulate weak bases with a pKa higher than the pH of the compartment. Various cellular organelles, such as lysosomes, secretory granules, and perhaps Golgi, have a pH of about 5, whereas the parietal cell when stimulated should have a pH of about 1. Thus, a weak base with a pKa of 4 should accumulate exclusively in the secretory canaliculus. This would allow specific targeting as well as selectivity.

George Sachs, Pump Blockers and Ulcer Disease, 310 New Eng. J. Med. 785, 786 (1984).

Defendants argue that the Sachs article taught one of ordinary skill in the art that to design an effective PPI, the compound should have a pKa of 4. Defendants claim that a drug's pKa is an indication of how well a chemical compound can survive an acidic environment and thus, such is relevant to the drug's accumulation and stability. As discussed supra at note 8, the parietal cells in the human stomach have a pH of 1, and thus, are the most acidic areas of the body. As a PPI travels throughout the body, it might encounter slightly acidic environments with a pH level as low as 5. Thus, according to Defendants' interpretation of the Sachs article, the goal is to adjust the pKa to a level which would render the compound stable enough to survive the pH5 regions of the body, but not so stable as to be unreactive in the pH1 parietal cells, where the compound needs to react to inhibit acid

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[19] ATPase is another term for the proton pump.

production. The Sachs article purportedly teaches that a compound with a pKa of 4 would achieve this result. Defendants further argue that the Sachs article suggested that to lower the pKa of a compound, one should lower the pKa of the pyridine nitrogen.

Plaintiffs claim that the Sachs article had nothing to do with pH5 stability. According to Plaintiffs, the factors that precisely determined stability were unknown at the time and thus, the article did not teach anything in regard to pH5 stability. Plaintiffs argue that the Sachs article only dealt with adjusting the compound's pKa to drive accumulation of the compound in the parietal cells. Accumulation, according to Plaintiffs, deals with getting the PPI compound to the proper location in the stomach, while stability deals with the compound's activity once it accumulates in different parts of the body. Further, Plaintiffs contend that even if one reads the Sachs article as Defendants suggest, such would have taught one of ordinary skill in the art to modify compound 12 by substituting a methoxy group for a methyl group at the 5-position of the pyridine ring, not at the 3-position, thus teaching the use of omeprazole's pyridine structure as a basis for an effective PPI.[20] Plaintiffs also claim that the stability of the compound depends on not only the pKa of the pyridine ring, but also on the pKa value of the benzimidazole ring, and thus, the Sachs article did not provide a roadmap to the development of pantoprazole.

The Court finds that Defendants' interpretation of the Sachs article is sufficiently persuasive to raise a substantial question of obviousness at this preliminary stage of the proceeding.[21] Dr. Sachs admits, in his deposition testimony, that the implication of his article is that an effective PPI would be

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[20] For a diagram of the structure of omeprazole, see Teva's Opposition Brief at page 10.

[21] Plaintiffs' counsel concedes that Plaintiffs are not entitled to a preliminary injunction if Teva's obviousness argument is sufficiently persuasive. See Oral Argument Transcript (July 31, 2007) at 10:5-14, 137:23-139:12; see also Plaintiffs' Oral Argument Handout (July 31, 2007) at p. 7 (citing PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996)).

stable at environments with pH5 levels: "It may be implied if you were to it, oh, well, Sachs means that, you know, we should keep the drug stable at pH 5, but it's not stated explicitly in here." See Sachs Deposition (Jan. 17, 2007) at 46:10-12. In conjunction with this admission, in which Dr. Sachs states that his article implies that the pKa is relevant to both selectivity and stability, Dr. Sachs also admits in his deposition that the key to accumulation of drugs in the parietal cells is the pKa of the pyridine ring, not the benzimidazole pKa value. Dr. Sachs deposition testimony was as follows:

> Q: In any event, when you wrote this article, you were essentially intending people reading the article to understand that to selectively accumulate this drug in the parietal cell, you should try to get the pKa of that pyridine nitrogen around 4?
>
> A. Correct.

Sachs Deposition (Jan. 17, 2007) at 52:16-21. Thus, based on the foregoing, the Court preliminarily finds that Sachs presented the requisite motivation for one to modify compound 12 to create pantoprazole by lowering the pKa of the pyridine ring to a pKa of 4.

Dr. Bryson's article, entitled "The Ionization Constants of 3-Substituted Pyridines, 3-Substituted Quinolines and 4-Substituted Isoquinolines," undisputably taught the pKa values of various chemical groups, including methoxy groups, at the 3-position of a pyridine ring.[22] See Dr. A. Bryson, The Ionization Constants of 3-Substituted Pyridines, 3-Substituted Quinolines and 4-Substituted Isoquinolines, 82 J. Am. Chem. Soc. 4871 (1960). According to Bryson, the pKa value of a methoxy group at such a position is 4; however, the pKa of a methyl group at this position is 5. Defendants argue that this information, coupled with the teachings of the Sachs article, suggested the creation of a PPI compound superior to compound 12 by substituting a methoxy group for a methyl group at the 3-

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[22] Defendants also claim that, in addition to the Bryson article, other articles teach chemists how to adjust the pKa of the pyridine ring. Since Defendants rely principally on Bryson, and only mention these other such articles in passing, the Court herein focuses on the Bryson reference.

position of the pyridine ring, thus resulting in a compound with a pKa of 4. Plaintiffs contend that Defendants simplify the teachings of Bryson. They argue that Bryson taught the pKa values of several chemical groups, many of which had low pKa values and would have been potential PPI substituents. Further, Plaintiffs claim that Bryson dealt only with the pKa values of simple pyridine structures, not complex pyridines, which are found on the PPI backbone.

Even accepting that Bryson dealt with simple pyridines and that Bryson disclosed that several other compounds had low pKa values and thus, might have been potential substituents for the pyridine ring of the PPI backbone, Defendants' interpretation of Bryson is sufficiently persuasive, at this stage of the litigation, to support an obviousness claim. Bryson undisputably taught that a compound with a methoxy group at the 3-position of the pyridine ring would have a lower pKa value (namely, a pKa of 4) that a compound with a methyl group at that position. Furthermore, as Defendants point out, the patent application for omeprazole teaches that several compounds, including hydrogen, methyl, and methoxy groups, can be substituted on the 3-position of the pyridine ring. See United States Patent Application No. 4,255,431 ("The present invention relates to novel compounds of the formula . . . wherein . . . R^3, R^4, and R^5 are the same or different and are each hydrogen, methyl, methoxy . . . ."). Since methoxy, according to Bryson, results in a lower pKa, such is the logical substitution. When Bryson's teachings are combined with the structure of compound 12 and combined with Dr. Sachs's teachings, Defendants have raised a substantial question that this combination was at the very least obvious to try and that such would lead to a predictable variation of compound 12, i.e., a compound with better pH5 stability. See KSR, 127 S. Ct. at 1740 ("If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, section 103 likely bars its patentability.").

Finally, the Court must consider whether any secondary considerations, or objective indicia of

non-obviousness, such as the failure of others, a long-felt and unresolved need for the drug, commercial success, unexpected results, and commercial acquiescence, are sufficient to rebut a prima facie showing of obviousness. See, e.g., Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1380 (Fed. Cir. 2006). The Court finds the evidence set forth during the instant proceedings, which again, the Court emphasizes are *preliminary* in nature, insufficient to rebut Defendants' substantial defense as to prima facie obviousness. First, contrary to Plaintiffs' representations, there has been no commercial acquiescence in the validity of the '579 patent. At least three generic drug companies, Teva, Sun, and KUDCo., see supra note 13, have all filed ANDA applications alleging that the '579 patent is invalid, unenforceable, and/or that they are not infringing such patent. Furthermore, Plaintiffs have not shown that the undisputed commercial success of Protonix is due to the drug's superior properties, as opposed to other factors such as marketing, discounting, and offering incentives to buyers.

In addition, Plaintiffs' claims of unexpected properties of pantoprazole—superior pH5 stability and the ability to irreversibly bind to a particular amino acid target in the proton pump, cysteine 822—are insufficient to overcome Defendants' preliminary showing of obviousness at this juncture of the litigation. First, if Sachs teaches pH5 stability via lowering the pKa of the pyridine ring, and Bryson teaches how to lower such pKa, then the purportedly unexpected property of pantoprazole is in fact an expected property. Since Examiner Fan did not consider the Sachs or Bryson articles in ultimately allowing the '579 patent to issue, presumably on the basis of the unexpected property of superior pH5 stability, her findings should not be afforded any particular deference, see supra note 16. With regard to cysteine 822 binding, Plaintiffs' own expert, Dr. Sachs, stated in a recently published article, "Clinical Pharmacology of Proton Pump Inhibitors," that cysteine 822 binding did not translate into clinically meaningful differences among the PPI drugs. See George Sachs, J.M. Shin, & C.W.

Howden, Review Article: Clinical Pharmacology of Proton Pump Inhibitors, 23 Aliment. Pharm. & Ther. 2, 5 (2006). These findings, at this preliminary stage of this matter, further support the Court's conclusion that Plaintiffs have not shown a likelihood of success on the merits.

Furthermore, while Plaintiffs make viable arguments as to the real-world creation of pantoprazole, including the story of Dr. Kohl, who purportedly created pantoprazole while moonlighting as a synthetic chemist, and the discussion of hundreds of other scientists, at Altana and elsewhere, who failed to produce a similar PPI compound, Defendants' real world facts are sufficiently persuasive as to the obviousness of pantoprazole. Compound 12 was first synthesized on March 22, 1984. See Plaintiffs' Reply Brief at p. 5 n.1; Teva's Oral Argument Handout (July 31, 2007) at tab 16. This is the same date that the Sachs article was published. See Teva's Oral Argument Handout (July 31, 2007) at tab 16. Dr. Kohl claims he first mapped out a synthesis scheme for pantoprazole only several weeks later, in May 1984. See Kohl Declaration at ¶ 23; Teva's Oral Argument Handout (July 31, 2007) at tab 16. On June 16, 1984, Altana disclosed pantoprazole in a Swiss patent application. See Lockner Declaration, Exhibit 2, at pp. 8299, 8306. In this application, Altana represented that pantoprazole had superior pH5 stability than prior art compounds. See United States Patent No. 4,758,579, at p. 1 ("A further object is to provide chemically-stable compounds and compositions which have a wide therapeutic range and lack substantial side effects and especially impart higher chemical stability to pyridylsulfinyl-benzimidazoles.").[23] However, pantoprazole was undisputably not synthesized until eleven months later on April 25, 1985. See Plaintiffs' Oral Argument Handout (July 31, 2007) at pp. 21-22; Teva's Oral Argument Handout (July 31, 2007) at tab 16. Defendants' point is this—if pantoprazole was not synthesized until almost a year after Altana represented that pantoprazole

[23] This statement, from the '579 patent, was made in identical form in the Swiss Patent Application for pantoprazole. See Oral Argument Transcript (July 31, 2007) at 66:19 - 67:16.

had superior pH5 stability, then how did Altana know it would have such stability? According to Defendants, Altana knew that pantoprazole would have superior pH5 stability compared to compound 12 and the other prior art compounds because of the teachings of Sachs and Bryson.[24] This timeline, which is undisputed by Altana, provides sufficiently persuasive evidence that pantoprazole was a predictable variation of compound 12 and thus, is evidence of obviousness, at this stage of the litigation. See KSR, 127 S. Ct. at 1740 ("If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, section 103 likely bars its patentability.").

Thus, for the foregoing reasons, the Court finds that Plaintiffs have failed to establish a likelihood of success on the merits. Again, the Court emphasizes that this determination is preliminary and thus, does not reflect whether Defendants will carry their burden at trial to prove invalidity based on clear and convincing evidence. See, e.g., Novartis Corp., 2007 WL 1695689, at *3 & n.8.[25]

B. Irreparable Harm

Plaintiffs have the burden of demonstrating that they will be irreparably harmed if their motion

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[24] An excerpt from the notebook of Dr. Ernst Sturm, an Altana scientist who is listed as an inventor on the '579 patent with Dr. Kohl, further supports Defendants' position. This notebook entry, submitted by Teva, shows that Dr. Sturm was tinkering with the PPI backbone by picking substituents, including a methoxy group, and calculating which substituents resulted in favorable pKa levels.

[25] The Court does not consider whether Defendants' inequitable conduct defenses, as set forth in their respective answers, raise a substantial question as to the validity of the '579 patent. Neither Teva nor Sun raised this defense in response to Plaintiffs' preliminary injunction motion, preferring instead to rest their arguments on obviousness and obviousness-type double patenting defenses.

Furthermore, since the Court has found that Plaintiffs have failed to demonstrate that Defendants' obviousness defense lacks substantial merit, the Court declines to consider the merit of Defendants' obviousness-type double patenting defense. Even if Plaintiffs were to succeed in establishing that the obviousness-type double patenting defense lacks substantial merit, Plaintiffs have not shown a likelihood of succeeding on the obviousness defense, and thus, Plaintiffs cannot meet their burden on the first factor of the preliminary injunction analysis. Accordingly, any inquiry into the merits of such a defense would be premature at this time.

for a preliminary injunction is not granted. The Court need not consider whether Plaintiffs are entitled to a rebuttable presumption of irreparable harm and whether such presumption, which was previously applied by the Federal Circuit, survived the United States Supreme Court's decision in eBay Inc. v. MercExchange L.L.C., 126 S. Ct. 1837 (2006). Such a presumption, if it is even still valid in light of eBay, would only be applied where a plaintiff makes a *clear* or *strong* showing of likelihood of success on the merits. See, e.g., Amazon.com, 239 F.3d at 1350; Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1363 (Fed. Cir. 2001). Since, as discussed above, Plaintiffs have not met their burden of showing likelihood of success on the merits, they certainly have not made a clear or strong showing of such success and thus, they would not be entitled to the presumption.

In an attempt to meet their burden, Plaintiffs argue that they have established irreparable harm because, if this Court denies Plaintiffs' preliminary injunction motion (1) both Altana and Wyeth will suffer irreversible price erosion, loss of substantial profits (Protonix purportedly makes up 50-60% of Altana's worldwide profits and makes up 8.8% of Wyeth's profits), and an unrecoverable decrease in market share and pricing; (2) Altana will also suffer an inability to service its debts, the layoff of employees, and the loss of research opportunities; and (3) Wyeth will also suffer "possible layoffs," the halting of pediatric development of Protonix, and the loss of research opportunities.

Defendants argue in response that Plaintiffs have failed to establish irreparable harm because, should this Court later determine that Defendants infringed the '579 patent, any harm can be adequately compensated by calculable monetary damages. Teva has affirmatively represented that it can pay any money damages award to Plaintiffs. Although Sun has not made such an affirmative representation, Plaintiffs have never contended that Sun is unable to pay a money damages award to Plaintiffs should this Court later determine that Sun infringed the '579 patent. Furthermore, Defendants contend that Plaintiffs' purported harms—loss of revenue, price erosion, decrease in

market share, loss of research opportunities, reduction in workforce, inability to satisfy debts—are speculative and thus, not cognizable harms. Sun also points out that some of Plaintiffs' purported harms, such as a reduction in workforce and inability to service debts, occur to third parties and not to Plaintiffs. Specifically, a forced reduction in workforce harms the employees that are laid off, and Altana's inability to satisfy its debts is really a harm to Nycomed, the company which acquired Altana on December 31, 2006. Nycomed is not a party to this litigation.

This Court finds that Plaintiffs have failed to establish irreparable harm. First, it appears that Plaintiffs' argument that their businesses will be financially crushed by the launch of generic versions of Protonix is exaggerated. With respect to Wyeth, Plaintiffs' counsel admitted during oral argument that Protonix makes up only 8.8% of Wyeth's annual sales. See Oral Argument Transcript (July 31, 2007) at 57:24 - 58:4. Although Protonix makes up a large portion of Altana's sales, Altana has known for over three years, since the generic drug companies filed their ANDA applications, that the Hatch-Waxman Act stays as to Teva and Sun would be expiring in August and September 2007. It is difficult to accept that Altana does not have a business plan in place to deal with the introduction of a generic version of Protonix, whether that includes Altana's marketing of its own authorized generic version of Protonix or some other business strategy.[26] The '579 patent expires in July 2010. If one accepts Altana's argument, the company will essentially cease to exist upon expiration of the '579 patent. This cannot be the case. Additionally, it is unreasonable to believe that Nycomed, which clearly knew of

[26] Plaintiffs asserted during oral argument that they have no intention of launching an authorized generic version of Protonix to compete with other generic entries. See Oral Argument Transcript (July 31, 2007) at 59:22-25. However, Altana's Executive Vice President, Dr. Schwartz, stated to investors on October 12, 2005, that Altana's plan was to "navigate pantoprazole *successfully* through an early 'loss of exclusivity' by launching an authorized generic 'with a partner,' among other strategies." See Altana Pharma Global Franchise Strategy (Oct. 12, 2005) at p. 16. Plaintiffs admitted during oral argument that the irreparable harm analysis "would be a different analysis" if Plaintiffs planned on launching an authorized generic. See Oral Argument Transcript (July 31, 2007) at 59:22-25.

this litigation and the expiration of the Hatch-Waxman Act stays as to Teva and Sun in August and September 2007 when it purchased Altana last year, sought out and approved a corporate transaction that would cripple the company upon expiration of such stays only several months after the acquisition.[27]

Furthermore, the Federal Circuit, as well as courts in this district, have declared that the types of harms advanced by Plaintiffs in the instant lawsuit are not irreparable and thus, cannot form the basis for granting an injunction. In Eli Lilly and Co. v. American Cyanamid Co., 82 F.3d 1568, 1578 (Fed. Cir. 1996), the Federal Circuit held that a movant does not establish irreparable harm by arguing loss of revenue and loss of research and development opportunities where money damages are calculable and the defendants have the ability to pay any damages award. In particular, in Eli Lilly, the court affirmed the district court's refusal to grant a preliminary injunction for such reasons, specifically stating that:

> If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make that same claim and thus be equally entitled to a preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy available whenever the plaintiff has shown a likelihood of success on the merits. For that reason, adopting the principle that [plaintiff] proposes would "disserve the patent system."

Eli Lilly, 82 F.3d at 1578 (quoting Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990)). This language is in line with an earlier Federal Circuit decision in Nutrition 21 v. United States, in which the court stated:

[N]either the difficulty of calculating losses in market share, nor speculation that such

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[27] Altana refused to produce copies of documents that Nycomed reviewed as part of its due diligence efforts prior to acquiring Altana to the Defendants. Altana withheld these documents on the basis of attorney-client privilege. This discovery dispute is currently pending before Judge Cecchi.

> losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial . . . . Indeed, the district court's reliance on possible market share loss would apply in every patent case where the patentee practices the invention. Moreover, [defendant] is acknowledged to be a large and financially responsible company which would be answerable in damages.

Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991). Two recent decisions from this district are in line with Eli Lilly and Nutrition 21. See Novartis v. Teva, Nos. 04-4473, 06-1130, 2007 WL 1695689, at *26-28 (D.N.J. June 11, 2007) (finding that plaintiff failed to establish irreparable harm because the damages were calculable, Teva had the ability to pay any monetary damages judgment, and the possibility of a loss of market share, irreversible price erosion, and lost research opportunities do not constitute irreparable harm); In re Gabapentin Patent Litigation, Nos. 00-2931, 01-1537 (D.N.J. Aug. 20, 2004 (JCL)), Transcript at pp. 12-14 ("Loss of market share, of price erosion, lost sales, and even lost market opportunities in my view can be reduced to dollars, not easily, but feasibly. And as Ivax well knows, it enters the market at its peril, if there is a finding of infringement and validity, and it is entitled to take that risk.").[28]

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[28]The Court recognizes that the Federal Circuit has reached certain decisions which may conflict with the language used in Eli Lilly and Nutrition 21. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1381-83 (Fed. Cir. 2006); Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1565-66 (Fed Cir. 1996). In both of these cases, the Federal Circuit indicated that the district court *did not clearly err* in finding that the plaintiff established irreparable harm by arguing some of the same types of harms Plaintiffs allege here—loss of revenue, loss of research opportunities, irreversible price erosion, etc. It does not appear that such decisions contradict Eli Lilly or Nutrition 21. Instead, the Federal Circuit's decisions in Bio-Technologies and Sanofi-Synthelabo illustrate the fact that the Federal Circuit reviews the district court's findings in this regard with deference and only overturns a district court's exercise of its discretion on the issue of irreparable harm if such was *clearly erroneous*. See Novartis Corp. v. Teva Pharm. USA, Inc., Nos. 04-4473, 06-1130, 2007 WL 1695689, at *27 (D.N.J. June 11, 2007) (citing to Sanofi-Synthelabo and stating that "[a]lthough there might exist many examples of courts granting preliminary injunctions where these factors were present, it does not necessarily follow that the possibility of such factors in such matters *demanded* a preliminary injunction. Similarly, the possibility of these factors in the instant matter does not alone demand a preliminary injunction, especially where such losses, by all measure, appear to be calculable").

Accordingly, the Court finds that Plaintiffs have not established irreparable harm and thus, are not entitled to a preliminary injunction.

C. Balance of the Hardships and Public Interest

Since Plaintiffs have failed to establish likelihood of success on the merits and irreparable harm, the Court declines to consider the last two factors of the preliminary injunction analysis. See, e.g., Amazon.com, Inc., 239 F.3d at 1350 ("a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm"); Polymer Technologies, Inc. v. Bridwell, 103 F.3d 970, 973-74 (Fed. Cir. 1996) ("a trial court need not make findings concerning the third or fourth factors if the moving party fails to establish either of the first two factors").

IV. Conclusion

In conclusion, the Court denies Plaintiffs' motion for a preliminary injunction. The parties in this case agreed, on July 31, 2007, that no party would sell a generic version of Protonix prior to September 7, 2007. The purpose of such an agreement was to give the Court time to issue its decision on the preliminary injunction motion. Since the Court has herein reached its decision, and denied Plaintiff's request for a preliminary injunction, the parties are now permitted to launch generic versions of Protonix upon obtaining the requisite FDA approval. An appropriate order accompanies this opinion.

Date: September 6, 2007

s/ Jose L. Linares
United States District Judge